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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,682	03/17/2004	Akira Asakura	13735 US1 (C038435/010970)	9826
7590	10/20/2005		EXAMINER	
Stephen M. Haracz, Esq. BRYAN CAVE LLP 1290 Avenue of the Americas New York, NY 10104-3300			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,682

Applicant(s)

ASAKURA ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 9, 20-22, 25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9, 20-22, 25, and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The examiner acknowledges Supplemental Amendment filed July 21, 2005 and Response to Office Action of May 16, 2005. Claims 1, 2, 3, 9, 25, 29, 30 and 31 have been amended. Claims 4-8, 10-19, 23-24 and 26-27 were previously canceled. Claims 1-3, 9, 20-22, 25, 28-31 are pending and are the subject of this Office Action.

DETAILED ACTION

1. Restriction/election

Applicants' conformation of election of the invention of the polypeptide embodied by SEQ ID NO: 8, which includes claims 1-3, 9, 20-22, 25 and 28-31 is acknowledged.

1. Priority

Acknowledgment is made of Applicants' statement that the priority document EOP 96115991.8 filed September 19, 1996 was filed together with the parental application 08/934,506.

Applicants turn the examiner's attention to the fact that the instant specification was amended on March 17, 2004 to recite the continuing application data. The examiner acknowledges this amendment, however the amendment is not correct because it misses the fact that Application 09/470,667 is now allowed, and the U.S. Patent No. is 6,730,503.

2. Objections

2.1. Specification

Objections to the specification for not complying with the requirements of 37 CFR 1.821-825 is withdrawn, because the specification has been amended accordingly, and Applicants filed a new version of the sequence listing and disk.

2.2. Claims

Claim 9 is objected to for the language "an enzyme produced by vector". A vector is unable to produce an enzyme. A host cell produces an enzyme by expressing a vector. The examiner suggests the language "an isolated enzyme produced by expression of vector".

3. Rejections

3.1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-3, 9, 29-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; *Diamond v. Chakrabaty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein or nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

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3.2. 35 USC, section 112, second paragraph

Rejection of claims 1-3, 20-22, 25, 28-31 made in the Office Action of Dec. 10, 2004 (previous action) under 35 U.S.C. 112, second paragraph, is withdrawn because the claims have been amended.

3.2. 35 USC, section 112, first paragraph

2.1.1. Lack of written description

Claims 2-3 and 9 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Rejection withdrawal

Rejection of claim 9 made in the previous action for lack of the description of biologic deposit is withdrawn, because *E. coli* HB101 carrying plasmid pSSB103R was deposited with accession No. DSM 17359 on June 2, 2005. Rejection of claim 2 and 3 is withdrawn, because Applicants arguments are found persuasive.

2.2.2. Scope of enablement

Rejection withdrawal

Rejection of claim 9 made in the previous action is withdrawn because the claim has been amended.

Rejection remaining

Claims 1-3, 20-22, 25, 28, 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the alcohol and aldehyde dehydrogenase of SEQ ID NO: 5, 6, 7, and 8, does not reasonably provide enablement for any amino acid sequence comprising a sequence that has at least 80% identity to SEQ ID NO: 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The reasons for this rejection have been explained in the previous action.

In addition, claim 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the plasmid comprising genes encoding SEQ ID NO: 5 and SEQ ID NO: 8 (plasmids pSSAB201 and pSSBA201), does not reasonably provide enablement for an enzyme that comprises a combination of at least two amino acids sequences each of said sequences being selected from the group of SEQ ID NO: 8 and SEQ ID NO: 5 and amino acid sequences that are at least 80% identical to SEQ ID NO: 8 or SEQ ID NO: 5. The reasons for this rejection were explained in the previous action. The main conclusion has been: without a further guidance on the part of Applicants related to the structure of chimeric enzymes, one skilled in the art is forced to construct numerous combination of co disclosed sequences or Sequences that are at least 80% homologous to them, express the chimeric proteins, examine the enzymatic activity of the expressed constructs with a low probability of success. Thus the experimentation left to those in the art is undue.

Response to Applicants' traverse

Applicants position is, "Table 7 clearly provides evidence that the Applicants enabled the full scope of the amended claims by unambiguously identifying a small number of enzymes having highly homologous polypeptide sequences and sharing a common function – AADH activity. Accordingly, it is respectfully submitted that undue experimentation would not be required to carry out the currently claimed invention", REMARKS, page 16, the last line and the first paragraph of page 17.

Applicants' argument has been fully considered but is found not persuasive for the following reasons. Table 7 quotes the homology of SEQ ID NO: 5-8 to each other. This, however, does not provide for structural identification of the enzyme having the AADH activity and being at least 80% homologous to any of SEQ ID NO: 5, 6, 7, 8. As Applicants rightfully emphasize, this is "a small number of enzymes" and not four genera or any combination of fourth genera as broadly claimed. For that reason the invention as claimed is not enabled and imposes undue experimentation on a skilled artisan.

3. Conclusion

No claim is in condition for allowance.

As allowable subject matter has been indicated in the previous action, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

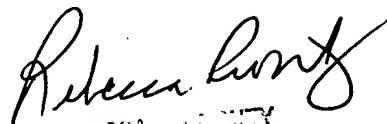
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-1600. The fax phone number for this Group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 872-9306.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

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